

A large, stylized graphic of a human figure, possibly a woman, is the central element of the cover. The figure is composed of two main colors: a deep navy blue and a light beige. The head, neck, and upper torso are in beige, while the rest of the body, including the arms and legs, is in blue. The figure is positioned in the upper right quadrant of the cover. The background is a solid deep navy blue.

HUMAN
FERTILISATION

EMBRYOLOGY
AUTHORITY

ANNUAL
REPORT
1992



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Foreword by the Chairman, Professor Colin Campbell

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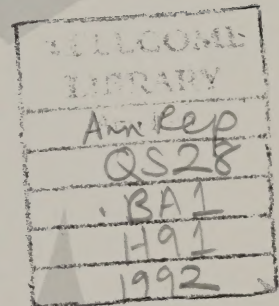
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INFORMATION CENTRE

24 MAY 1993

Wellcome Centre for Medical Science

FOREWORD

In 1990, Parliament passed the Human Fertilisation and Embryology Act. A new Authority to regulate the field of assisted conception was established under the Act and its first members were invited to serve in the Autumn of 1990. When the Act received Royal Assent on 1 November of that year, the members had already begun preparatory work with a view to taking on their full statutory responsibilities in August 1991.

The first year of our operation has been an intensely busy period, involving the Authority in very interesting, often difficult, tasks. Overall we have been engaged in designing a national regulatory system. Setting up a new organisation and designing a new system are never easy matters. In the case of the Human Fertilisation and Embryology Authority, there were particular problems to be solved. We were working with a long and complex Act of Parliament; an extensive body of secondary legislation had to be drafted; we had to design a system of regulation governing the provision of treatment by professional people not much used to legislative control; we had to work in areas involving sophisticated scientific and medical practices which attracted rigorous ethical debates; and we had just nine months in which to shape and implement the new system.

While some of us were new to this area, we did not have to work entirely in the dark. The Interim Licensing Authority (ILA) was a source of valuable information and advice. The ILA had been operating effectively for a number of years a voluntary licensing system for centres carrying out *in vitro* fertilisation and embryo research. However, our brief is wider than that of the ILA. The Act of Parliament establishes the framework within which we must operate, and it prescribes that, in addition to IVF and embryo research, we have to control the storage of gametes and embryos and the practice of donor insemination in all its forms. Also, we have duties in respect of the inspection of centres and the maintenance of a central register of information. These increase significantly the size and complexity of our operations. Sometimes I wonder if, when the Bill was introduced into Parliament over two years ago, anyone truly appreciated the complicated nature and extent of the Authority's remit!

Looking back over the year, I am pleased to say that we have achieved all that I could have hoped for and perhaps rather more. Our comprehensive Code of Practice was published in July 1991 and it was, generally, very well received. By 1 August, we had received 157 licence applications and we had designed a robust system for dealing with them.

What all of this has meant for members of the Authority is that they have had to work immensely hard to get the Authority up and running. It is through the commitment and dedication of the Authority members and our Executive that we have accomplished so much. I am grateful to each and every member and to all the staff for the way they have confronted the various challenges and met them. Their professionalism has been of the highest standard.

Despite the work that has been completed, we are still a new body and we still have much to do. We are well into our first programme of inspections and have begun to take decisions on licence applications. Licensing will be a continuing task each year. We have also begun to collect the information that is required by the Act and we are introducing secure systems for the storage of that information.

In this report, there are references to a number of ethical and policy issues which we must consider in the coming year. Further ahead, new developments in science and medicine will pose fresh questions. It is to be expected that there will be new debates since public interest in this area remains strong. This is as it should be. We deal with a fascinating area where medical and scientific advance continues apace and yet where we must always pay attention to human concerns about the implications of new developments.

Parliament decided to establish this Authority. One of our duties is to ensure that the medical and scientific advances are used in ways which best serve the interests of society and of those people who seek to rely on them to help fulfil their desire for a family. We have, in our first year, tried to determine the structures which will allow this.

This Authority is the first, and so far the only, one of its kind in the world. We are conscious that many eyes are upon us both at home and abroad. We will fulfil the wishes of Parliament and maintain a national system in which the very highest possible standards in the provision of fertility treatment are achieved. We intend to guard these high standards closely to ensure that the legitimate interests of patients, donors and resulting children are properly protected.



Professor Colin Campbell,
Chairman

Colin M. Campbell

Colin M. Campbell

Chairman

1. INTRODUCTION

1. This is the first report of the Human Fertilisation and Embryology Authority (the "HFEA" or the "Authority"). It is published in accordance with section 7 of the Human Fertilisation and Embryology Act 1990. The report outlines the background, functions and structure of the Authority, describes the licensing system which it has introduced, and gives details of the issues which it has addressed over the past year and of those which it will need to consider in the coming year.

This, being its first annual report, necessarily describes much of the work involved in setting up the Authority. It is important to stress, however, that the aims and objectives which underlie this preparatory work have been continually present in the minds of members - that is, to put in place a system which will promote high standards of practice, and one which will best serve the interests of all those involved.

1.1 Background to the Authority

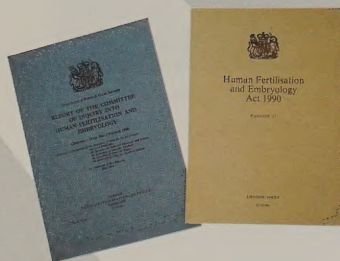
The history of the Human Fertilisation and Embryology Authority is often traced back to 1978 and the birth of the world's first "test-tube" baby. Certainly that first successful *in vitro* fertilisation (IVF) provided impetus to the sequence of events which led to the establishment of the HFEA, but the Authority's remit also extends to donor insemination (DI) and embryo research. Technological advances in assisted conception had raised important questions about their social and ethical implications, and the public and parliamentary debates which followed are already well documented.

While DI is a practice which is known to have been in use for very many years, the ethical and legal questions surrounding it, especially those relating to the legal status of the child and its parents, were as keenly debated in Parliament as were many of the issues surrounding IVF.

The notion of a statutory body to oversee the practice of certain advanced assisted conception techniques and of embryo research emerged with the publication in 1984 of the report of the Committee of Inquiry into Human Fertilisation and Embryology (the "Warnock" report). Despite going through two major rounds of consultation and extensive debate in both Houses of Parliament, the Warnock Committee's proposals for such an Authority remained broadly intact. It is a tribute to Baroness Warnock and her committee that the Authority now established is virtually that which was envisaged some seven years previously.

The foresight of the Medical Research Council and of the Royal College of Obstetricians and Gynaecologists is also to be admired, for it was they who, in 1985, set up the Voluntary (later to become "Interim") Licensing Authority for Human In Vitro Fertilisation and Embryology (ILA).

For six years the ILA operated, under the Chairmanship of Dame Mary Donaldson, an effective voluntary licensing system for centres carrying out IVF and embryo research. The legacy of the ILA includes a body of information and experience which was of considerable value to the HFEA.



1.2 Main functions of the Authority

The principal statutory function of the HFEA is to regulate certain practices involved in the treatment of infertility and research on human embryos. Specifically, it is required to operate a licensing system for all centres carrying out one or more of the following activities:

- storage of gametes (eggs or sperm) or embryos;
- research on human embryos;
- any infertility treatment which involves the use of donated gametes; and
- any treatment which involves the creation or use of embryos outside the body.

The Authority is empowered to issue three kinds of licence - for treatment, for storage, or for research.

A second major function of the Authority is to maintain a central register of all such treatments given, of all people born as a result of treatment, and of all donors.

The Authority has a number of other statutory duties, including:

- publicising the services which the Authority provides and those which licensed centres provide;
- giving advice and information to centres where appropriate;
- publishing a Code of Practice giving guidance to centres on how they should carry out licensed activities; and
- giving information and advice to donors and prospective donors, to people seeking treatment or storage, or to people considering whether to do so.



Unfertilised egg

1.3 Preparations for 1 August 1991

The Authority's licensing powers and other responsibilities under the Act took effect on 1 August 1991. However the Act allowed for a transitional period during which centres could continue providing services although they had not yet received a licence.

There were a number of key tasks which the Authority had to complete by 1 August 1991. To achieve these the Authority had to work to a very tight schedule. The first of the tasks was to publish the Code of Practice.

The Act required the Authority to submit a draft of its first Code of Practice to the Secretary of State within twelve months of coming into existence (ie by 7 November 1991). However, as centres would be expected to behave as if they were licensed from 1 August 1991, the Authority decided that it would be highly desirable to publish the Code by that date, even though extensive public consultation was involved.

The second task was to have the licensing system in place by 1 August 1991. There were two reasons for this. First, the Authority was asking centres to apply for licences by 1 August 1991. It would not be reasonable to ask centres to apply for a licence when they knew nothing of the procedural requirements. Second, the Authority had to be in a position to be able to determine all initial licence applications by 31 July 1992, the date on which the transitional period would expire.

A third task, related to the licensing system, was to discuss with the Department of Health the terms of the transitional arrangements. Regulations were subsequently made whereby treatment and storage centres which were in operation before 1 August, and research projects which were being conducted before that date and which held a current licence from the ILA, could continue for up to one year in anticipation of holding an HFEA licence. In all cases an application to the HFEA had to be made by 1 August, and only those activities which were being carried on before 1 August could continue to be carried on under the transitional provision.

A further task was the setting of fees to be charged to applicants. The Act requires that a fee is paid with each application, and that an additional fee be charged prior to the actual issue of the licence. The fee structure and levels also had to be approved in advance by the Secretary of State for Health and the Treasury.

Finally, it was necessary to design and operate systems for the collection of data about all IVF and DI treatments performed in licensed centres, and about patients and donors. This involved preparing directions to centres regarding the recording of information and the forms on which they could provide returns to the Authority.

In order to present all relevant advice and guidance in a comprehensive way, the Authority issued to all centres a loose-leaf "Manual for Centres" at the same time as the licence application forms were distributed in June 1991; sections covering each of the above items were added by the end of July 1991.

2. STRUCTURE OF THE AUTHORITY

2.1 Membership of the Authority

There are 21 members of the Authority, including the Chairman and the Deputy Chairman; they are listed at the end of this report. The members are appointed by the Secretary of State. There are no specified upper or lower limits to the number of members. The Act requires that the Chairman and Deputy Chairman must not be medical practitioners or be otherwise involved in any capacity with treatment or research activities. However it stipulates that between one third and one half of the other members of the Authority **should** be medical practitioners or otherwise involved in such activities. The membership demonstrates the broad range of interests that are represented on the Authority, including medical, scientific, nursing, legal, religious and social interests.

2.2 Number and frequency of meetings

The Authority first met in October 1990. Up to and including the meeting held on 7 November 1991, there were 14 meetings of the full Authority. So far it has been the Authority's general policy to meet monthly, and it will continue to do so for as long as this is necessary.

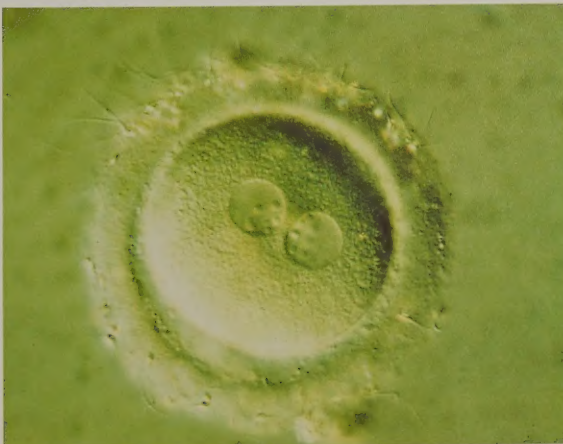
2.3 Committee structure

Because of the volume of work to be undertaken within the Authority's first year, various committees were established. The committees have carried out detailed and preliminary work on behalf of the Authority. All major decisions are made by the Authority as a whole.

The following committees were established during the year:

- Licensing and Fees Committee
- Code of Practice Committee
- Information Committee
- Organisation and Finance Committee
- Committee on Social and Ethical Issues

The membership of these committees is listed at the end of the report, and their objectives and work during the year are described in chapters 6 to 10. There are, in addition, and in accordance with the requirements of the Act, a number of licence committees which determine licence applications.



Fertilised egg (zygote)

3. LICENSING



2 - cell embryo

3. By 1 August 1991 the Authority had received 157 licence applications. Of these 114 were applications for treatment licences, 36 for research licences and 7 were for storage licences only. At Annex 1 is a list of those centres from which applications were received. This list represents a complete set of the treatment, research and storage centres which were operating on 31 July 1991. Current research projects are listed at Annex 2. If any centre now carries out a licensable activity without having submitted an application to the Authority it is committing an offence under the Act.

With a transitional period of one year from 1 August 1991, the Authority was effectively set a target for determining all of the initial licence applications. The programme of inspections began, at a rate of 3-4 per week, in November 1991, and a cycle of inspections and licence committee meetings has been established so that for this and for future years applications can be disposed of efficiently and effectively.

The schedule has been arranged so that the initial inspection programme will be completed by mid-June 1992. This will allow all applications to be determined by 31 July.

The most important aspect of the licensing process is the need to ensure fairness and consistency. The Authority has established a number of procedures to ensure that these objectives are achieved and it will continuously monitor the operation of the process.

All HFEA inspectors (see page 15 and Annex 3) and members receive training about the Act, about the Code of Practice and about the nature of the inspection process.

All inspection teams are issued with standard checklists and the chairman of each inspection team is given a standard brief on the procedure to be adopted. The inspector-coordinators, who are members of the Authority's Executive, draft inspection reports according to a standardised format, and then seek the approval for the report of their fellow inspectors. The reports are then presented to the Authority's licence committees.

Licence committees consist of members of the Authority. They follow the requirements of the Act and relevant regulations. They receive detailed information on each centre and its activities such that they can consider applications efficiently and consistently.



Licence committee members Ian Cooke, Richard Holloway and Brenda Hoggett

4. The ILA collected data on IVF between 1985 and July 1991. The 1990 data have been analysed and basic information is included in this Annual Report. The section has been divided into three parts, the first giving pregnancy and live birth rates, the second looking at multiple pregnancies and the third looking at success by woman's age and indications for treatment. The presentation of the data follows the format previously used by the ILA. A fuller analysis of the data and a comparison of the statistics collected during the six years the ILA was in existence has been published separately and is available from the HFEA.



4. IVF TREATMENT DATA

4.1. IVF Data 1990

In order to give a reasonably detailed analysis, the 64 IVF centres have been grouped into three categories - those performing more than 400 IVF treatment cycles per year (large centres), those performing 100 - 400 treatment cycles (medium centres) and those performing fewer than 100 cycles (small centres). Of the 35 small centres, nine performed five or less cycles and a further 7 centres each performed less than 20 cycles.

Table 1 shows the total number of recorded IVF cycles and their outcomes. The number of patients undergoing IVF treatment in 1990 increased to 9,964 compared with 8,790 in 1989 and the number of treatment cycles increased from 10,413 to 11,583. There were only 57 pregnancies where the outcome was unknown, representing less than 3% of all pregnancies.

Table 1 IVF Data 1990 - TREATMENT				
	PATIENTS	TREATMENT CYCLES	EGG COLLECTIONS	EMBRYO TRANSFERS
Large centres (8)	5218	6165	5131	4276
Medium centres (21)	3814	4365	3751	3162
Small centres (35)	932	1053	947	757
TOTALS (64)	9964	11583	9829	8195

Table 1 IVF Data 1990 - OUTCOME					
	PREGNANCIES	LIVE BIRTHS	ABORTIONS	ECTOPICS	PERINATAL DEATHS
Large centres (8)	1198	876	223	49	14
Medium centres (21)	672	484	134	13	22
Small centres (35)	134	83	44	3	2
TOTALS (64)	2004	1443	401	65	38

The number of live births refers to the total number of pregnancies resulting in at least one live baby, not the total number of babies born. As in previous years the perinatal mortality rate is high: 19 per thousand pregnancies compared to 8 per thousand in the general population (England and Wales, 1990); this is most probably accounted for by the higher than average number of multiple pregnancies (see tables 4-6).

Table 2 shows the mean pregnancy and live birth rates by size of centre. Overall the larger centres have higher success rates, but the ranges show that this is not the case for all centres. Between all clinics there is a very wide variation in the success rates, with a range in medium and large centres of between 2.1 and 23.3 live births per 100 treatment cycles.

Table 2 Mean Pregnancy Rates 1990 - PREGNANCY RATES %						
	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE
Large centres	19.4	2.7 - 29.3	23.3	3.7 - 32.7	28.0	5.9 - 37.0
Medium centres	15.4	3.5 - 28.6	17.9	4.0 - 31.4	21.3	6.2 - 32.9
Small centres	12.7	0.0 - 45.0	14.1	0.0 - 46.2	17.7	0.0 - 52.9
Overall	17.3		20.4		24.5	

Table 2 Mean Live Birth Rates 1990 - LIVE BIRTH RATES %						
	PER TREATMENT CYCLE	RANGE	PER EGG COLLECTION	RANGE	PER TRANSFER	RANGE
Large centres	14.2	2.1 - 22.9	17.1	3.0 - 24.4	20.5	4.7 - 28.4
Medium centres	11.1	2.3 - 23.3	12.9	2.9 - 24.7	15.3	3.6 - 26.6
Small centres	7.9	0.0 - 33.3	8.8	0.0 - 33.3	11.0	0.0 - 50.0
Overall	12.5		14.7		17.6	

Both the IVF pregnancy and live birth rates per treatment cycle given in Table 3, show an increase over the six years from 1985-1990.

Table 3 IVF Pregnancy and Live Birth Rates per Treatment Cycle 1985-1990						
ALL CENTRES	1985	1986	1987	1988	1989	1990
Pregnancy Rates %	11.2	9.9	12.5	12.9	15.4	17.3
Live Birth Rates %	8.6	8.6	10.1	9.1	11.1	12.5

* Excluding one large centre with incomplete data

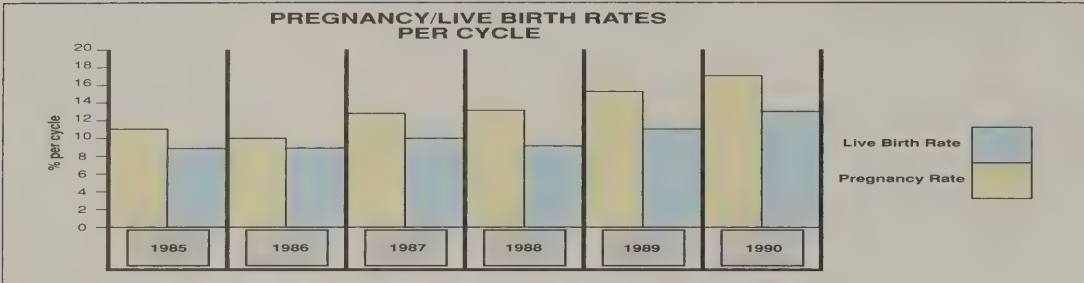


Table 4 Multiple pregnancies with IVF 1990	
PREGNANCY	RATE %
Singleton	74.4
Twin	21.9
Triplet	3.6
Quad	0.1
Overall Multiple Pregnancies	25.6

4.2. Multiple Pregnancies

The overall multiple pregnancy rate for IVF was 25.6% (Table 4) compared with 26.8% in 1989 (ILA Annual Report 1991). Whilst the actual number of triplet pregnancies has increased slightly from 65 in 1989 to 69, as a percentage of all IVF pregnancies the rate has reduced. The number of quadruplet pregnancies has reduced from three in 1989 to one in 1990.

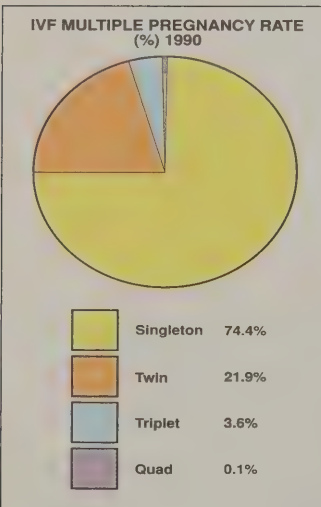


Table 5 shows the number of embryos transferred in each of the 8,195 embryo transfers performed. The majority of cycles (55.3%) involved the transfer of 3 embryos, and in 613 transfers (7.5%) four embryos were replaced. There were no IVF cycles performed in 1990 where more than four embryos were replaced (the ILA's guidelines allowed the transfer of three embryos, or, in exceptional circumstances, four).

Table 5 Multiple pregnancy and Embryo Transfer 1990					
EMBRYOS TRANSFERRED	NO OF TRANSFERS	SINGLETON	TWIN	TRIPLT	QUAD
One	1184	79	1	0	0
Two	1867	343	102	2	0
Three	4531	882	286	59	0
Four	613	100	22	8	1
Five or more	0	0	0	0	0
TOTAL	8195				

Table 6 shows that, as in previous years, the pregnancy rate increased according to the number of embryos transferred up to the transfer of three embryos, but when four embryos were transferred the pregnancy rate dropped.



NO OF EMBRYOS TRANSFERRED	PREGNANCY RATE %	MULTIPLE PREGNANCY RATE%
One	6.8	0.1
Two	23.9	23.3
Three	27.1	28.1
Four	21.4	23.7
Five or more	0.0	0.0

4.3. Success by age and indications for treatment

Table 7 shows the pregnancy rates and live birth rates by woman's age, divided into five-year age groups. The results follow the same pattern as in 1989, with the group of patients most likely to become pregnant being those aged 25-29 and the least likely, those over 45 years of age. It can be seen that the variations between ages 25 and 39 is fairly small, but there is a marked decrease in success when the woman reaches 40 years.

	UNDER 25	25 -29	30 - 34	35 - 39	40 - 44	45+
No of cycles	195	1938	4465	3723	1122	70*
PREGNANCY RATE %						
Per cycle	15.9	20.9	19.6	16.2	7.8	2.9
Per transfer	24.2	27.3	26.2	23.0	12.3	4.9
LIVE BIRTH RATE %						
Per cycle	9.7	15.2	14.7	11.4	4.0	0.0
Per transfer	14.8	19.9	19.8	16.0	6.3	0.0

* This may include cycles using eggs from a younger donor.

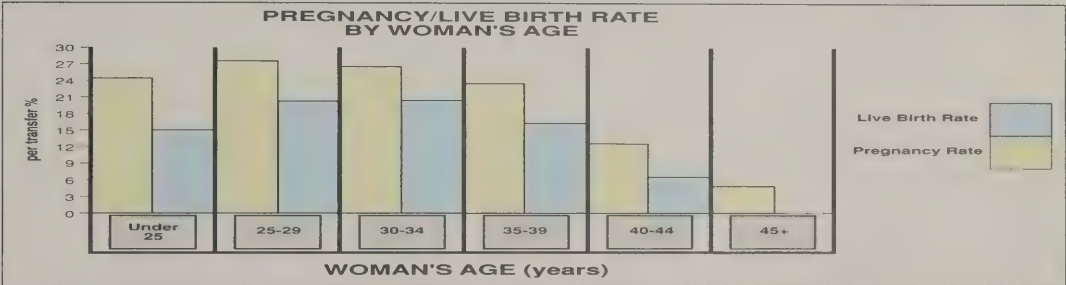


Table 8 shows the success rates according to indications for treatment. The number of cycles presented in this table exceeds the total number of cycles performed because in some cases there was more than one indication for treatment; the success rates have been adjusted to take account of this. Again, the results are very similar to those obtained in 1989. Although the rates for all types of infertility have increased, they do not vary considerably between the different indications.

	NO OF CYCLES	PREGNANCY RATES%		LIVE BIRTH RATES %	
		PER CYCLE	PER TRANSFER	PER CYCLE	PER TRANSFER
Tubal	6437	18.3	24.1	12.7	16.8
Endometriosis	1227	18.0	25.5	13.7	19.4
Male factor	2861	15.9	24.6*	11.3	17.4*
Unexplained	2372	15.3	22.2	11.8	17.1
Cervical factors	192	15.1	21.7	10.9	15.5
Ovarian and other	1383	17.1	25.0	12.7	18.6

* Includes cases in which donor sperm were used.

Since 1 August 1991, the HFEA has been collecting IVF data similar to that collected by the ILA. While we shall therefore be able to provide comparable data so that longer term trends in success rates can continue to be assessed, we shall also be reviewing the way in which the data is presented. Data on all treatments involving the use of donated gametes will also become available in future years.

5. THE WORK OF THE HFEA

5. In addition to considering a regular flow of reports and recommendations from its committees, the Authority addressed a number of major issues during the year. Some of the more important of these are described below.

5.1 Confidentiality provisions of the Act

Section 33(5) of the Act prevents any person to whom a licence applies from giving identifying information about a patient or donor to any other person who is not covered by a licence, except in a few clearly defined circumstances. The penalty under the Act for an unlawful disclosure of such information is up to two years' imprisonment. While it is recognised that this restriction quite reasonably gives the patient an extra degree of control over information relating to their own treatment, it soon became evident that the extent of the restriction had consequences which were previously unforeseen and potentially dangerous.

The principal problem is that the centre is not able to give information to others directly, even with the patient's consent. Thus:

- where an emergency situation arises the licensed practitioner is prevented from giving potentially vital information to the doctor handling the emergency - this is a potential danger to the patient herself;
- clinicians are unable to communicate directly with a patient's GP or any other doctor who may have referred the patient or who may be otherwise involved in the patient's health care;
- other staff in a hospital, for example anaesthetists and theatre nurses, while not working directly for the licensed unit but participating in the general care of the patient, may not have access to relevant information;
- a clinician is not able to give proper instructions to a lawyer in a case where she or he is being sued by the patient.

The Authority has considered the confidentiality of patient information at some length. Some of the problems which have been raised are capable of some form of administrative resolution, albeit rather cumbersome, and the Authority has issued advice to centres wherever appropriate. The Authority recognised that it is right that the anonymity of current donors should be wholly maintained and that patients should retain control over the circumstances in which such sensitive information about themselves should be given to others. However, it seems clear that the Act is more restrictive than Parliament intended - it could surely not have been the wish of Parliament that patients' lives might be endangered, or that doctors should be prevented from being able to defend themselves in a court of law or before the General Medical Council.

In considering this important issue the Authority sought the views of a number of other bodies, such as the Royal College of Obstetricians and Gynaecologists, the General Medical Council and the British Medical Association.

The Chairman of the Authority then wrote to the Minister of State for Health on 14 November 1991 expressing the Authority's concern and urging the Government to introduce amending legislation which would control the disclosure of patient information under section 33(5) of the Act in a more sensible way, while retaining the principle that the **patient** should have control over who has access to the information.

5.2 Use of embryos created before 1 August 1991

In order to fulfil its obligation under the Act to maintain a register of patient and donor information, the Authority issued directions to licensed centres instructing them that no donor sperm (including instances where sperm had already been used to create an embryo which was subsequently frozen) should be used in treatment after 1 August 1991 without the donor's name being provided to the Authority for entry on the central register.

It soon became apparent that these directions might cause problems with the continued supply of donor sperm, since many donors prior to 1 August had not given their permission to their names being disclosed to anyone. Some centres reported that attempts to contact previous donors to obtain their permission had failed either because they could no longer be traced or because once contacted they refused to allow their names to be forwarded to the Authority. If sperm from new donors was to be properly screened and quarantined, it would take at least six months to build up a new supply of donor sperm.

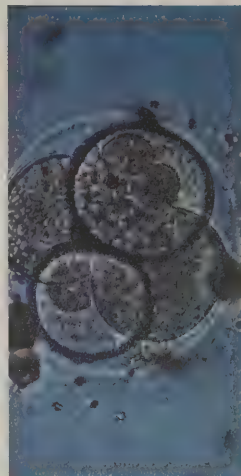
A related issue was that there was evidently a significant number of embryos which were created using donated sperm and stored before 1 August which could not now be used because the donors' names could not be supplied to the Authority.

The Authority therefore agreed to certain amendments to the directions on information requirements so that:

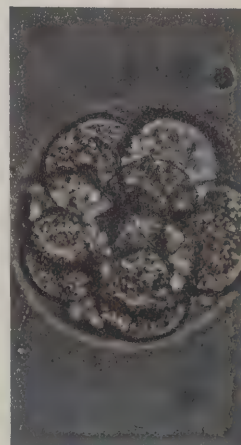
- embryos produced with donor gametes and in store on 1 August could be used without supplying the donor's name; and
- gametes already in store on 1 August could be used between 1 October 1991 and 31 March 1992 without supplying the donor's name; and
- gametes already in store on 1 August could be used without supplying the donor's name in order to provide a woman with a full sibling for an existing "donor" child provided that the Authority received written notification of the woman's request by 31 March 1992.

In each of these cases the donor's name may only be omitted if the name is not known to the centre or to any other centre, or the centre has not been able to trace the donor to obtain his agreement despite reasonable efforts to do so, or the donor has refused to allow the disclosure of his name to the Authority.

The Authority allowed this relaxation of the information requirements in respect of donors' names for gametes and embryos stored before 1 August 1991 to maintain continuity of service during the transition to the new statutory system, and to ensure that embryos could be used in treatment instead of being allowed to perish.



4 - cell embryo



8 - cell embryo

6. THE LICENSING AND FEES COMMITTEE



Diana Brittan, LFC Chairman

6. The terms of reference of the Licensing and Fees Committee (LFC) were:

“To recommend to the Human Fertilisation and Embryology Authority systems and procedures for the licensing and inspection of treatment, storage and research facilities - for the grant, variation, revocation and suspension of licences; to produce associated guidance for applicants, inspectors and licence committees; and to determine the fees that will be charged to licensees and applicants by the Authority in the pursuance of its statutory functions.”

Its role was essentially to prepare recommendations to the Authority for a fee structure and for the Authority's licensing system. The committee first met on 16 November 1990 and subsequently met 10 times before 1 August 1991.

6.1 Licensing

At its first meeting the committee set out what it considered to be the main objectives of the licensing procedure:

- i. to ensure that no prohibited activities take place and that no activities for which a licence is required are undertaken except under licence;
- ii. to secure public confidence and the confidence of centres that the Authority is maintaining a fair and consistent framework for licensing;
- iii. to assure the public and Parliament that the research work which is undertaken under licence is necessary, within the conditions set out in the Act; and
- iv. to assure the public that centres operate to certain minimum standards.

There were various stages and elements of the licensing system which, to comply with the Act, had to be addressed. These were the transitional licensing arrangements, application forms, inspection procedures, licence committee procedures, and guidance for centres on the licensing system.

Transitional arrangements

The LFC recommendations were accepted by the Department of Health. A transitional period of one year was introduced, so that centres could continue to operate until 31 July 1992 or until their licence application was determined by a licence committee of the Authority. All initial applications have to be determined within one year from 1 August 1991.

Treatment centres were therefore able to continue performing those activities which they were carrying out prior to 1 August, and research projects in progress by 1 August could continue provided they had previously been licensed by the ILA. In all cases an initial application to the HFEA had to have been made by 1 August 1991.

Application forms

The licence application forms which the LFC produced, and which the Authority now uses, were designed with the requirements of the Act and of the Code of Practice in mind. They request information about the centre's staff, premises, patient information leaflets, consent forms, record forms, operating procedures, charges, and, where appropriate, the centre's ethics committee. It was important to gather a comprehensive set of information from the outset so that inspection teams and licence committees could be fully informed about each centre.

Inspection procedures

The LFC took as a basic model the inspection procedures and checklists that had been used by the ILA. It agreed that an inspection team should normally consist of a clinician, a scientist, a "lay" member (who might have a background in nursing, counselling, or some other related discipline), and a member of the Authority's Executive. Each team should contain at least one HFEA member, the remainder being drawn from a pool of expert inspectors appointed by the HFEA. A list of HFEA inspectors is at Annex 3.

In order to ensure consistency, a standard format is followed in the conduct of all inspections and in the inspection reports which are presented to the Authority's licence committees. Checklists reflecting the structure and content of the Code of Practice are therefore given to all inspectors before each visit.

Licence committee procedures

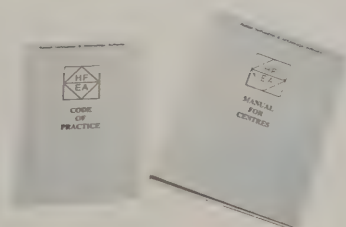
Much of the procedure for the conduct of licence committees is set out in the primary legislation. Section 10 of the Act also provides for regulations to be made by the Secretary of State about licence committee procedures. The LFC submitted its views on necessary regulations to the Department of Health, and proposed further guidance on aspects of the procedure not covered by the regulations.

Guidance for centres

Once the application forms and the inspection and licensing procedures had been drawn up, the committee felt that it would be helpful to centres if they were to be given appropriate guidance. The Authority accordingly produced a comprehensive Manual for Centres which covered not only inspection and licensing procedures, but which also contained the Code of Practice, fees information, directions, and details of the transitional arrangements.



Hugh Whittall,
Deputy Chief Executive





Dr Steven Hillier,
HFEA and LFC member

6.2 Fees

Under section 16(5) of the Act the level of fees is that amount "as may be fixed from time to time by the Authority with the approval of the Secretary of State and the Treasury".

Ultimately the structure and levels to be charged would be determined by the Government, but the committee's initial task was to prepare proposals for the Authority to present to the Department of Health.

When the issue was discussed in Parliament the Government stated that it would expect the Authority to raise two thirds of its costs through charging licence fees, the remainder to be funded by the Treasury. However, the costs of the Authority had been underestimated when the Bill was prepared, and a number of duties which the Authority is now to perform were added during the course of the Bill's passage through Parliament, adding significantly to the cost of running the Authority. The Authority noted that the level of fees would have some bearing on the overall provision and cost of treatment services, and therefore took the view that it would no longer be reasonable to require centres to meet two thirds of the Authority's costs.

A further initial principle on which the recommendations were based was that the fees should be distributed fairly amongst licensed centres, so that the fee should be related to the size of the centre. This precluded any system under which a standard fee could be charged for each type of licence.

The Authority therefore decided on a structure whereby centres would pay a relatively small initial fee on application, and that the additional fee should be based on the number of treatment cycles performed in the previous year, with different rates for IVF and DI treatments. This was submitted to the Department of Health in April 1991, together with a recommendation that the Authority should be required to raise no more than 30-40% of its own costs.

The Secretary of State and Treasury approved the proposed structure, but imposed a requirement that the Authority raise 50% of its costs through fees. This approximates to the proportion of the costs attributable to the licensing function. It is this outcome which now applies.

Licences are issued annually, with an initial fee on application of £250 for treatment licences, and £100 for research or storage licences. The largest part of the fees income will, however, be raised through additional fees charged to centres, based on the numbers of treatment cycles performed in the year prior to application.

The current rates are £30 per IVF cycle and £7 per DI cycle. These figures were calculated on the basis of the total revenue to be raised by the Authority in relation to estimates of the total number of cycles currently being performed. ILA data from recent years indicated a figure of around 12,000 IVF cycles per annum. There are not at present, however, any centrally collected data on the number of DI treatments being performed. The committee estimated, on the basis of the number of DI centres then believed to be in operation, and on the basis of data collected by the Royal College of Obstetricians and Gynaecologists from a sample of these centres, that around 30,000 DI treatments are being carried out each year.

The future rates of fees per IVF and DI treatment cycle may vary according to:

- i. any requirements imposed by the Secretary of State and the Treasury;
- ii. the costs of running the Authority, and in particular its licensing function; and
- iii. the actual total number of treatment cycles being carried out each year, once these figures have been established.

6.3 Future work of the LFC

The committee has completed its initial task of establishing a fee structure and the licensing system. However it will continue to monitor the effectiveness of these systems, based on feedback from centres, from inspection teams, from licence committees and from members of the Executive. Its overall aim is to ensure that the licensing system is fair and consistent, and that it achieves the set objectives.



HFEA Inspection

7. THE CODE OF PRACTICE COMMITTEE



Professor Brenda Hoggett,
CoPC Chairman

7.1 Code of Practice - legal requirements

The Authority is required by section 25 of the Act to: “maintain a Code of Practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom a licence applies”.

Section 25 continues:

“The guidance given by the Code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child’s need for a father), and of other children who may be affected by such births.

The Code may also give guidance about the use of any technique involving the placing of eggs and sperm in a woman.”

7.2 Code of Practice Committee - the process

The Code of Practice Committee (CoPC) was established at the first Authority meeting to prepare a draft Code of Practice. The Authority would circulate the draft for consultation, revise it where necessary and present it to the Secretary of State for approval. This was to be achieved in time for the Code to be published before 1 August 1991.

The committee first met on 26 October 1990, and, in preparing its draft, met again on 13 subsequent occasions.

The draft finally approved by the Authority was issued for consultation on 21 March 1991. The consultation document was accompanied by an explanatory document which gave the reasons and assumptions underlying it.

About 1,000 copies of the consultation document were issued, and by 20 May, when the consultation period expired, the Authority had received over 200 responses from centres, statutory, voluntary and professional bodies, and from individuals. As a result of these, the Authority made a number of changes to its original proposals. However, the consultation document was generally very well received and there were no areas which needed radical reassessment.

The Code was submitted to the Secretary of State in July 1991 and, having received his approval, was published and distributed on 30 July.

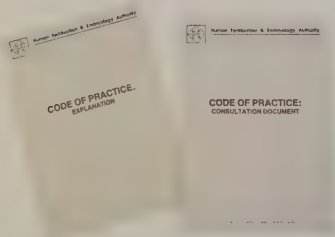
7.3 Code of Practice - objectives

The ILA had articulated a set of guidelines for IVF treatment and embryo research centres which operated prior to 1 August 1991. However, the scope of the Act meant that the HFEA’s Code of Practice had to be both longer and more comprehensive than the ILA guidelines. Parliament have decided the statutory framework within which centres should operate and which the Authority must elaborate with further guidance.

The introduction to the Code of Practice states that:

“The object of the Code is wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions. In framing it we have been guided both by the requirements of the Human Fertilisation and Embryology Act and by:

- the respect that is due to human life at all stages in its development;



- the right of people who are or may be infertile to proper consideration of their request for treatment;
- a concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and
- a recognition of the benefits, both to individuals and to society which can flow from the responsible pursuit of medical and scientific knowledge.

We recognise that these considerations may sometimes conflict and have sought to reconcile them in a way which is both practicable and in accordance with the spirit and intentions of the Act. Our aim is to support the best clinical and scientific practice, while guarding against the undoubted risk of exploitation of people at a time when they may be particularly vulnerable.”

Failure to comply with the Code does not of itself give rise to legal liability, nor is compliance automatically a condition of a licence. However, the Authority expects centres to comply with the Code unless they can show that there is good reason for not doing so in a particular case. The Authority’s licence committees must take breaches of the Code into account when considering whether or not there has been a breach of licence conditions and may do so when considering whether or not to vary or revoke a licence.

7.4 Code of Practice - content

In many areas the Code of Practice restates what is already accepted as good clinical or scientific practice. For example, it outlines minimum qualifications which should be held by key staff in centres; it follows existing guidance on laboratory practice; provides guidelines agreed with the Department of Health on HIV screening; and it requires the availability of backup and emergency clinical facilities. In other areas, however, the Code gives guidance which arises directly out of the Act. The following paragraphs summarize the main contents of the Code of Practice and briefly outline the Authority’s reasoning in establishing them.

Staffing

In order to ensure an appropriate level of expertise the Code of Practice sets out minimum levels of qualifications which should be held by clinical, nursing, counselling and scientific staff. In some cases, such as in counselling and in embryology, there are as yet no specific qualifications which are directly relevant, and the requirements are relatively flexible so that account can be taken of a person’s previous experience.

Welfare of the child

The Act requires centres, before deciding whether or not to offer treatment, to take account of “the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth” (Section 13(5)). The Act also requires the Authority’s Code of Practice to give guidance about how centres should consider the welfare of the child.



6 - day old embryo
(blastocyst)

The Code addresses this issue specifically. It states that the centre should establish who the legal parents of the child would be and take a medical and social history from each prospective parent. It identifies a number of particular factors that centres should take account of in considering the welfare of the child, and it states that centres should, with the patient's consent, seek the view of the patient's GP before deciding whether or not to offer treatment.

The Act does not specify to whom treatment may or may not be given, and in particular it does not prohibit the provision of treatment for any category of women. Centres are expected therefore to assess prospective patients on an individual basis, using a multidisciplinary evaluation, considering the factors outlined in the Code, and balancing the interests of those involved very carefully, giving the weight they deserve to both the prospective parents and the child. Where a centre is concerned, it should make further relevant enquiries before proceeding with treatment.

Assessment of donors

The Authority decided that there should be age limits on donors, the lower limit being 18. The upper limit for women donating eggs was set at 35 because of the rapidly increasing risk of chromosomal abnormalities beyond that age. The limit of 55 on male donors was set because of the general decline in the quality of sperm with age.

The Authority has adopted existing medical and scientific guidelines on HIV testing, and issued jointly with the Department of Health specific guidance on HIV screening for gamete donors. This requires all donors to be screened, and in the case of donor sperm a quarantine period of 180 days is now required.

Information for patients and donors

A further requirement of the Act is that all potential patients and donors must be given "such relevant information as is proper". The Authority felt that it was highly important that all patients and donors be given as much information as is needed for them to make fully informed decisions, and they should be encouraged to ask for further information.

The Code of Practice therefore expands on the Act and gives advice on the kind of information that should be given both orally and in writing.

For patients this includes information about the treatment envisaged, its physical and practical effects, the availability of counselling, the cost of treatment and the likelihood of failure.

For donors the information should cover, amongst other things, the procedures involved, the need for HIV screening, anonymity, the availability of counselling and the need to register the donor's name with the Authority.

Consent

Consent to the use and storage of gametes and embryos is comprehensively covered in Schedule 3 to the Act. However, the Authority believes that guidance is also appropriate to help patients give fully informed consent to the treatment that they are about to be given. This consent should contain details of the nature of the treatment, and indicate that the patient has been given all of the relevant information referred to in the Code of Practice. The Authority has provided, as an Annex to the Code, a model consent form which centres are expected to use or at least to incorporate into their own consent forms.

Counselling

It is a requirement of the Act that counselling be offered to all patients and donors, and the Code of Practice gives thorough guidance on how it expects centres to fulfil their statutory obligation in this respect. The Authority believes that counselling is an integral part of the treatment process, and that it should not be considered a separate activity for those who have “problems”. Counselling has been covered in detail in the Code because of the relatively underdeveloped state of infertility counselling at present, and it draws extensively on the Kings’ Fund Centre Counselling Committee report “Counselling for Regulated Infertility Treatments”.

Three types of counselling are identified in the Code - implications, support and therapeutic counselling. All must be available either within the centre or by reference to specialist counselling outside the centre.

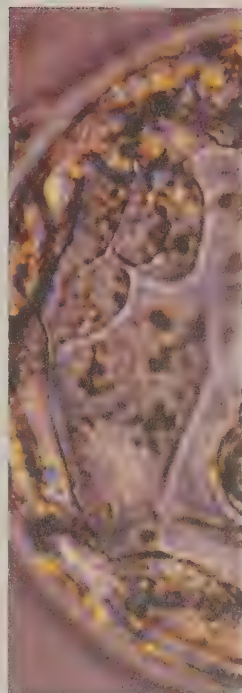
Counselling must be clearly distinguished from the giving of information and clinical advice. It should be available at all stages of the treatment process, and the centre should keep a record of all counselling offered and accepted.

Use of gametes and embryos

Two specific issues are addressed in this section of the Code which are of particular importance.

First, the Authority decided that the number of embryos or eggs which could be transferred during a single treatment cycle, whether IVF or Gamete Intra-fallopian Transfer (GIFT), should be limited to three. The guidance from the ILA had previously allowed four embryos to be transferred in exceptional circumstances. The Authority believes that there is no longer any clinical justification for transferring more than three in any circumstances. Indeed there are people who believe that the limit should be reduced to two. This is an issue which the Authority will continue to monitor.

The second issue is the maximum number of offspring to be produced using any one donor, and here the Authority decided that the limit should be ten - the same number as recommended by the Warnock Committee. Some people argued that this was too restrictive, and that 15 or 20 would be more reasonable. However, the Authority acknowledges that there may be concern among the public about the idea of one person producing very large numbers of offspring. It also recognises the need to prevent “eugenic” overuse of gametes from a donor with particular characteristics. There may, however, be rare exceptions to the limit of ten, such as where a patient wishes to have a second or subsequent child by the same donor. The Authority has asked to be notified of such cases.



6 - day old embryo
(blastocyst)

Research and ethics committees

The purposes for which embryo research may be allowed are clearly set out in the Act (Schedule 3, paragraph 3). The Code of Practice does add however a number of additional requirements, namely that the project must be supported by peer review by academic referees selected by the Authority, and that the project must have the support of a properly constituted research ethics committee.

The Authority has not insisted that treatment licence applicants must have the support of an ethics committee. It was felt that where centres found it helpful to seek the advice of an ethics committee on any particular case, as they have done in the past, they should be encouraged to do so. However, many of the centres now seeking licences do not have ethics committees on whose services they can call, and it was thought that it would be premature at this stage to include in the Code of Practice a requirement that they should all establish ethics committees to consider problems arising from treatment.

The Authority will monitor the involvement of ethics committees in treatment. The aim will be to help centres as far as possible to obtain ethical advice when required.

Reviewing the Code of Practice

The introduction to the Code stated that the Authority intends to “keep the Code under regular review, in order to ensure that it continues to give the clearest and most up-to-date guidance possible to centres in achieving all the objectives of the Act”. This review process will be a continuous one and will take account of any changes in public perceptions and of developments in practice.

8. THE INFORMATION COMMITTEE

8.1 Legal duties

Section 31 of the Act requires the Authority to keep a register of information relating to:

- the provision of treatment services for any identifiable individual;
- or
- the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman;
- or
- if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.

In addition, the Authority must provide advice and information for licensees, patients and donors, and must publicise the services provided to the public by licensed centres and by the Authority itself.

8.2 Register of information

The Authority established an Information Committee to consider what information the Authority needed to collect from centres to maintain a register of information for statutory and monitoring purposes, and to consider how that information should be collected and stored.

The following objectives were set to underpin the Authority's information collection activities:

- to enable the Authority to fulfil the statutory requirements laid down in the Human Fertilisation and Embryology Act 1990;
- to enable the activities governed by the Act to be monitored and evaluated;
- to enable the Authority to be able to meet reasonable requests for information about activities governed by the Act and publish an informative annual report;
- to enable the Authority to provide children over 18 (and in some circumstances over 16) who were born following treatment services with information about their genetic origins; and
- to assure the public that access to confidential information will be strictly controlled.

The committee decided that the most effective way to collect details of every treatment cycle would be to issue all licensed centres with forms which they would complete, keeping one copy for their own records and forwarding one to the Authority for entry in the register. This would allow the HFEA to build on the system already established by the ILA for IVF treatment data.

The forms were designed so that the information which they contained would be the minimum necessary to allow the Authority to answer questions from children born as a consequence of treatment services about their genetic backgrounds. They should also allow the Authority to monitor the performance of licensed centres and the provision of treatment services in general. Great importance was given in the design of the data collection system to avoiding unnecessary intrusion into the personal lives of patients and donors, and to avoiding unnecessary cost to centres and to the Authority.

In July 1991 the Authority issued data collection forms together with directions detailing the information which centres are required to supply to the Authority under the Act.



Professor Antony Cox,
Information Committee
Chairman



Embryologist at work with
micro manipulator

The information relates to:

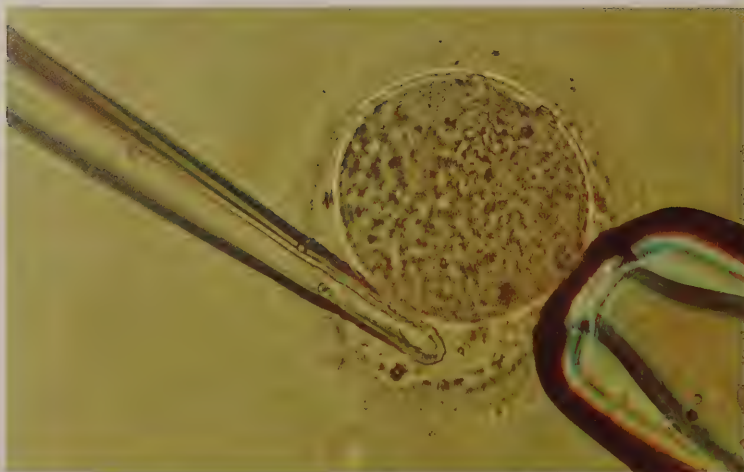
- IVF treatment cycles;
- DI treatment cycles;
- outcomes;
- donor information;
- embryo storage and research;
- consent to storage and use of sperm and embryos; and
- consent to use of eggs and storage of embryos.

8.3 Storage of information

Information held on the register which might identify any individual must be kept strictly confidential and may only be disclosed by the Authority in very limited circumstances. Any unauthorised disclosure of identifying information would be a criminal offence, carrying a penalty of up to two years imprisonment or a fine, or both. The Authority has therefore been conscious of the need to set up a secure system for the storage and retrieval of information to be held on the register. The Information Committee prepared detailed specifications of the requirements of the computer system that would be needed to maintain such a register. Computer consultants have been appointed and are working with the Authority's Executive in setting up a long-lasting and secure system. Access to the data will be strictly controlled.

8.4 Publishing of information

The Authority has made available information on egg donation, and will consider in the coming year what further information will be published about treatment services provided by licensed centres.



Egg undergoing sub-zonal insemination

9. The Organisation and Finance Committee (OFC) was established initially to arrange for the recruitment of a Chief Executive for the Authority, and to consider other staffing requirements. However, it became clear that there was a role for the committee in overseeing the overall management of the Authority.

The committee has inevitably been very busy in this, the first year of the Authority's existence. Amongst other things, it has scrutinised the Department of Health's proposals for a Management Statement for the Authority; overseen the preparation of the Authority's budget and its staff pension scheme; and approved on the Authority's behalf the appointment of several new members of the Authority's Executive staff, including two new inspector co-ordinators who were appointed at the end of 1991.

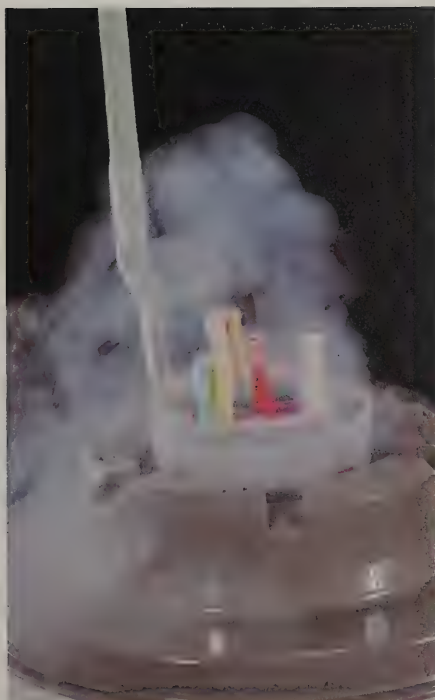
The Authority is currently moving to new, cheaper and more suitable premises, and the OFC has been closely involved in making the arrangements for selecting accommodation and effecting the move.



9. THE ORGANISATION AND FINANCE COMMITTEE



Professor Colin Campbell,
OFC Chairman



Storing frozen embryos



Blastocyst

10. THE COMMITTEE ON SOCIAL AND ETHICAL ISSUES



Liz Forgan,
CSEI Chairman

10. A key responsibility of the Authority is to consider and advise on issues which are of concern to centres, to the public, to Parliament and to the Authority itself. These may be of an ethical nature and relevant primarily to clinicians or other practitioners, or they may be of wider concern to society generally.

The field of assisted conception is one in which scientific development is currently moving forward at a great pace, and it is important that developments proceed in an environment of enlightened debate. The Authority intends to contribute to the debate.

There are a number of issues which the Authority must address in the near future, and there are others on the horizon which will also need to be considered before long. Undoubtedly there will be fresh issues, yet unknown, which will present themselves in the coming months and years.

10.1 Role and membership

The Authority has established the Committee on Social and Ethical Issues (CSEI) to study particular subjects in depth and to advise the full Authority.

The committee's terms of reference, taking account of the general requirements of the Authority, are as follows:

- to advise the Authority on social and ethical issues;
- to obtain and consider the facts of each matter;
- to identify the separate issues involved in each matter;
- to identify the various interests of all those involved for each matter;
- to consider different views in terms of argument and sentiment; and
- to work towards a steady and general point of view taking account of the Human Fertilisation and Embryology Act and based on moral reasoning.

10.2 Issues for consideration

There are a number of important issues which have been identified as deserving of consideration by the Authority and by the CSEI. These include:

Payments to gamete donors

The Act prohibits the payment of money or other benefits for gametes (eggs or sperm) except where allowed by the Authority. For the time being the Authority has issued directions which limit the value of money or other benefits which may be given, the intention being to maintain the status quo until a longer term consensus is established. The Authority will need to assess the possible effects of either removing the limitations or, if it wishes to ensure that altruism is the motivation for all gamete donations, of prohibiting any payment other than the reimbursement of reasonable expenses.

Sex preselection of embryos

It is now possible, through pre-implantation diagnosis, to determine the sex of an embryo, and, in some cases, to determine whether it is carrying a genetically inherited disease.

The therapeutic value of these diagnoses is that it is possible to identify those embryos which may be carrying the genetic defect involved in certain sex-related hereditary diseases, such as Duchenne's muscular dystrophy. Once the sex of an embryo has been determined, only those which are of the sex not susceptible to the particular disease will be replaced in the woman. These procedures have now been successfully introduced in one major IVF centre.

The issue for consideration is not so much the use of sex preselection for such therapeutic purposes, but rather the potential to which it gives rise for the selection for social reasons of the sex of children born as a result of IVF treatments. The same ethical issue arises out of any form of treatment, such as the separation of x- and y-chromosome carrying sperm, in which the sex of the resulting child can be selected in advance.

Donor anonymity

The Act allows the Secretary of State to make regulations about the information to be given to people who, having been born in consequence of the use of donated gametes and on reaching the age of 18, apply to the Authority for information about the donor or donors. At present the Authority cannot give identifying information, and the anonymity of donors is assured. However, the Government has said that it will consult widely on this issue, and the Authority will wish to take a view on whether for the future it would wish donors to be identifiable in this way. In any event the continued anonymity of anyone donating gametes prior to the making of such regulations is protected under the Act.

Surrogacy

Surrogacy arrangements are not illegal, though the law makes clear that any such arrangement is not enforceable in the courts. At present the Authority's Code of Practice only addresses surrogacy in requiring the centre to consider the welfare of the child in relation to both the carrying mother and the recipients, as it is possible that the child could become the legal child of either set of parents. The Authority will consider whether there are any other ethical aspects to surrogacy which it may wish to cover in the Code of Practice.

Use in research of fetal and other human tissue

Fetal tissue is already the subject of research in relation to its potential use in the treatment of some types of disease. There are currently questions about the possible study of fetal ovaries as a source of immature oocytes which might be capable of being matured in vitro and used in the treatment of some types of infertility. Similarly there is a potential for research into the use of immature oocytes taken from cadavers or from live donors for the same purpose. While it is probably some time before any such potential can be realised, the Authority is examining the ethical and social implications of using genetic material from these sources.

11. THE AUTHORITY'S EXECUTIVE



Flora Goldhill,
Chief Executive

11. When the Authority was first set up in November 1990 its Executive consisted of six staff provided by the Department of Health on secondment. Over the course of the following year this increased to twelve full-time and one part-time members of staff. There remain six people on secondment from the Department of Health, and one person is currently seconded from the Department of Social Security. However the Authority now directly employs six of its staff members, and this number is expected to increase as seconded personnel return to their original employers and are replaced by staff employed directly by the Authority.

The Authority advertised for a Chief Executive in November 1990, and appointed Flora Goldhill to the post on 4 February 1991. A Deputy Chief Executive, Hugh Whittall, with principal responsibility for overseeing the licensing and inspection process, was appointed in September 1991.

The remaining staff work essentially in three separate areas of operation: licensing and inspections (this includes four full-time inspector-coordinators); policy; and finance, personnel and administration.

With an escalating workload which will include running the computerised register of information the Authority expects to increase its staff to around 16 by Spring 1992.



HFEA Staff

12.1 General

Having achieved its main objectives for the first year - designing a comprehensive licensing system and publishing the Code of Practice - the Authority will be seeking to underpin the regulatory process with a set of common and rising standards.

It must be recognised that not all of the requirements of the Code of Practice can be achieved overnight in all centres, and the Authority appreciates that it will take a little time for relevant standards to be universally met. However, the Authority will be making exacting demands of any centres which it finds to be lacking, and it is prepared to refuse or withdraw licences from those which fail to make the necessary improvements within a reasonable timescale.

One of the key roles for the Authority is to protect patients from centres which fail to provide adequate services or which fail to observe the fundamental requirements of the Act. Over the coming year the Authority will impress upon centres the serious nature of these responsibilities and the need to follow the Authority's requirements.

12.2 Inspection and licensing

The inspection and licensing process is the function which lies at the heart of the Authority's regulatory powers. Not only is it used to ensure that proper standards are maintained, but it also assists in informing the Authority about current and developing practice in the whole field of assisted conception. As such it is a useful mechanism for gathering and disseminating information which will help continuously to raise standards of practice throughout the UK.

12.3 Confidentiality of patient records

Centres are prohibited under section 33(5) of the Act from disclosing identifying information about patients or donors to anyone who is not covered by a licence. There are several significant problems which result from this - eg, communications with patients' GPs are restricted; centres are unable to communicate with other local clinicians such as obstetricians; and doctors facing legal action from patients are unable to give full details of the case to their legal representatives. Pressure is growing for a change in the law. The Authority has already called for an amendment to the Act and hopes this will be implemented this year.

12.4 Gamete Intra-fallopian Transfer (GIFT)

Both the Authority and the Department of Health will be monitoring the use of GIFT. In particular the Authority will consider whether GIFT, because it is not licensed, is being used inappropriately instead of IVF.

12.5 Success rates

There have been many enquiries about whether the Authority will publish centres' success rates. There are clearly difficulties associated with publishing comparative success rates of centres, not least because these will vary according to factors such as the age profile of patients and the nature of the infertility which is being treated. However, the Authority has a duty to provide information to centres and to the public, and it will consider what information should be published and the way in which it should be presented.

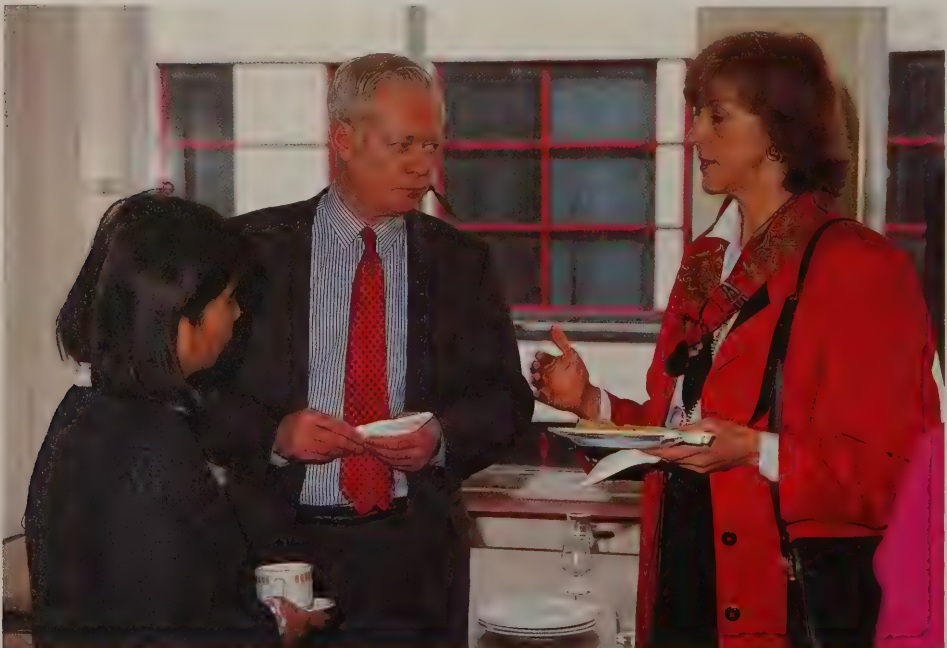
12.6 Training for counsellors and embryologists

The counselling requirements in the Code of Practice are greater than some centres are at present able to meet, not least because of a shortage of appropriately trained or qualified infertility counsellors. It is accepted that counselling provision will have to be developed over a period of time, but the Authority will need to consider what needs to be done to encourage this to happen, and whether any particular qualifications should be prescribed. It is possible that new courses in counselling for infertility will have to be developed.

Similarly, there are currently no clearly defined qualifications for embryologists, and the Authority will consider whether particular minimum qualifications can be identified, and what, if any, training should be prescribed.

12.7 Information

The Authority has a duty to provide information to centres and to the public. It will consider therefore what literature needs to be produced - eg. for prospective donors, for prospective patients, or for centres to display or to distribute to patients.



HFEA members Jeannette Naish, Ian Cooke and Diana Brittan

MEMBERS OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

Chairman	Professor Colin Campbell	Vice-Chancellor of Nottingham University
Deputy Chairman	Diana Brittan	Member of the Equal Opportunities Commission and a magistrate in the City of London
Members:	Margaret Auld	Formerly Chief Nursing Officer, Scottish Home & Health Department and Vice-President, Royal College of Midwives
	Professor Robert Berry	Professor of Genetics at the University of London
	Professor Ian Cooke	Professor of Obstetrics & Gynaecology, University of Sheffield Jessop Hospital for Women
	Professor Antony Cox	University of London Professor of Child and Adolescent Psychiatry at the United Medical and Dental Schools of Guy's and St Thomas' Hospitals
	Liz Forgan	Director of Programmes at Channel 4 Television
	Joan Harbison	Senior Lecturer in Education, Stranmillis College, Belfast
	Dr Stephen Hillier	Director, Reproductive Endocrinology Laboratory, University of Edinburgh Centre for Reproductive Biology
	Professor Brenda Hoggett	Law Commissioner; Recorder of the Crown Court and Visiting Professor of Law at King's College, London
	The Rt Rev Richard Holloway	Bishop of Edinburgh
	Dr Helen Houston	General practitioner and Senior Lecturer in Continuing Medical Education at University of Wales College of Medicine. Dr Houston resigned from the Authority in September 1991 and was replaced in January 1992 by Dr Jeannette Naish, general practitioner.
	Penelope Keith	Actress
	Angela Mays	Management Consultant
	Dr Anne McLaren	Director of the Medical Research Council Mammalian Development Unit
	Rabbi Julia Neuberger	Visiting Fellow, King's Fund Institute and former Chairman of the Patients' Association
	Professor Robert Shaw	Professor of Obstetrics and Gynaecology at the Royal Free Hospital School of Medicine
	David Shilson	Senior Official in the Bank of England
	Professor Robert Snowden	Professor of Family Studies at Exeter University
	Christine Walby	Director of Social Services, Stafford
	Professor David Whittingham	Professor of Experimental Embryology, University of London and Director of the Medical Research Council Experimental Embryology and Teratology Unit

LICENSING AND FEES COMMITTEE

Diana Brittan (Chairman)
Margaret Auld
Stephen Hillier
Richard Holloway
Angela Mays
Julia Neuberger
Robert Shaw
Dávid Shilson
Christine Walby
David Whittingham



MEMBERSHIP OF COMMITTEES

CODE OF PRACTICE COMMITTEE

Brenda Hoggett (Chairman)
Robert Berry
Ian Cooke
Antony Cox
Liz Forgan
Joan Harbison
Helen Houston (to September 1991)
Penelope Keith
Anne McLaren
Robert Snowden

INFORMATION COMMITTEE

Antony Cox (Chairman)
Angela Mays (from June 1991)
Christine Walby (to June 1991)
David Whittingham
David Birch (Co-opted member from
Office of Population Census and Surveys)

ORGANISATION AND FINANCE COMMITTEE

Colin Campbell (Chairman)
Diana Brittan
Robert Berry
David Shilson

COMMITTEE ON SOCIAL AND ETHICAL ISSUES (CORE MEMBERSHIP)

Liz Forgan (Chairman)
Margaret Auld
Colin Campbell
Joan Harbison
Stephen Hillier
Richard Holloway
Christine Walby

1. LIST OF CENTRES OPERATING UNDER THE TRANSITIONAL ARRANGEMENTS (TREATMENT(IVF/DI)/RESEARCH)

THE FOLLOWING CENTRES PROVIDE STORAGE FACILITIES ONLY:

ANNEXES

2. LIST OF CURRENT RESEARCH PROJECTS

King's College Hospital, London

Preimplantation stage diagnosis of sickle cell anaemia and haemophilia A in the human embryo

King's College Hospital, London

A study of the growth requirements of cell lines derived from parts of the human blastocyst

King's College Hospital, London

The definition of optimal culture conditions for the culture of human preimplantation embryos in vitro

King's College Hospital, London

The identification of criteria of human preimplantation embryo viability

St George's Hospital, London

Low temperature preservation of oocytes and embryos

St George's Hospital, London

Culture media and preimplantation development

St George's Hospital, London

Preimplantation stage diagnosis of sickle cell anaemia and haemophilia A

Royal Liverpool Hospital

Measurement of intracellular metabolites at fertilisation

Royal Liverpool Hospital

Immunobiological investigations into human fertilisation and implantation

Royal Liverpool Hospital

The definition of optimal culture conditions for human preimplantation embryo development in vitro

St Thomas's Hospital, London

The development of a contraceptive vaccine

St Thomas's Hospital, London

Methods for evaluating normality of preimplantation development

St Thomas's Hospital, London

Studies of methods for the cryopreservation of human oocytes

John Radcliffe Maternity Hospital, Oxford

Transplantation antigen expression on human preimplantation embryos

John Radcliffe Maternity Hospital, Oxford

Biopsy of human embryos for the preimplantation diagnosis of genetic disease

John Radcliffe Maternity Hospital, Oxford

The use of growth factors to improve human embryo culture for in vitro fertilisation

John Radcliffe Maternity Hospital, Oxford

Assisted hatching of human IVF embryos

John Radcliffe Maternity Hospital, Oxford

Partial zona dissection (PZD) and sub-zonal insemination for the alleviation of male infertility

University of Edinburgh

A study of the mechanism of trisomy formation in man

University of Edinburgh

Development of techniques and establishing a protocol for the microinsemination, by injection, of spermatozoa into oocytes (human)

Park Hospital, Nottingham

In vitro studies of human oocytes after microinjection of spermatozoa

University of Oxford

Growth and characterisation in vitro of cells derived from the early human conceptus

Ninewells Hospital, Dundee

Growth requirements of the human preimplantation embryo in vitro

Withington Hospital, Manchester

In vitro development and implantation of normal human embryos and comparison with uni- or poly- pronucleate embryos

Royal Victoria Infirmary, Newcastle

Evaluation of 3 different culture systems for human embryos

Bristol Maternity Hospital

Effects of substances and procedures on the ability of human spermatozoa to penetrate zona free hamster eggs

Lister Hospital, London

The use of partial zona dissection and perivitelline insemination in male factor infertility

Hammersmith Hospital, London

To measure the activity of metabolic enzymes in spare human preimplantation embryos

Hammersmith Hospital, London

To measure the activity of enzymes implicated in genetic disorders

Hammersmith Hospital, London

Sperm oocyte interaction and fertilisation failure

Hammersmith Hospital, London

Preimplantation genetic diagnosis parallel investigations

St Mary's Hospital, Manchester

Development of sub-zonal insemination: a technique to micro-inject sperm into oocytes as a treatment for male infertility

London Fertility Centre

Micromanipulation of human gametes in the treatment of male factor infertility: comparison of partial zona dissection and sub-zonal insemination

Bourn Hall, Cambridge

The cryopreservation of human oocytes

ANNEXES

3. LIST OF HFEA INSPECTORS

Professor John Aitken
Scientist - MRC Reproductive Biology Unit,
Edinburgh

Dr Linda Baggott
Lecturer in Biology, Exeter University

Dr Sarah Ball
Lecturer in Human Genetics, Exeter University

Professor P J Berry
Dept. of Paediatric Pathology, Bristol Royal Hospital
for Sick Children

Mrs Sarah Biggs
Previously Director of Child and Member of the
Kings Fund Committee

Dr Elizabeth Bryan
Medical Director, Multiple Births Foundation

Professor Peter Braude
Chair in Obstetrics and Gynaecology, St Thomas'
Hospital

Mrs Linda Breeze
Counsellor for National Childbirth Trust and RELATE

Dr Nigel Brown
Scientist, MRC, Experimental Embryology and
Teratology Unit London

Mr Charles Butcher
Solicitor, Chairman of the Ethics Committee for the
AMI Park Hospital, Notts and AMI Portland
Hospital, London

Mr C D Chandler
Clinician, Billinge Hospital, Wigan

Professor M Chapman
Reader in Obstetrics and Gynaecology, Guy's
Hospital, London

Dr Anne Clarke
Cellular Immunologist, Queens' Medical Centre,
University of Nottingham

Dr John Clarke
Lecturer in Zoology, Oxford. Formerly Chairman of
the Society for the Study of Fertility. Formerly a
Member of the ILA

Dr Sheila Cooke
GP with Family Planning Experience. Member of
BICA

Dr John Coutts
Reader in Reproductive Endocrinology, University of
Glasgow

Mrs Alwyne W Cox
Magistrate. Formerly member of National Council
for the Probation Service. Formerly a member of the
ILA

Dr Ruth Curson
Clinician, King's College Hospital, London

Professor G S Dawes
Formerly Director of Nuffield Institute for Medical
Research and formerly a member of the ILA

Mrs J Denton
Nursing Research Fellow, The Multiple Births
Foundation

Professor G R Dunstan
Emeritus Professor of Moral Social Theology in the
University of London. Formerly a member of the ILA

Ms Hillary Everett
Counsellor, St Bartholomew's Hospital

Dr R Fleming
Scientist, Glasgow Royal Infirmary

Professor S Franks
Professor of Reproductive Endocrinology, St Mary's
Hospital, London

Dr L Fraser
Scientist, Department of Anatomy, Kings College,
London

Rev R Gilles
St Andrews Rectory, Fife

Professor C Gosden
Clinical Cyto geneticist, MRC, Western General
Hospital, Edinburgh

Mrs H Hillier
Nurse, Edinburgh Royal Infirmary

Professor M Hull
Consultant Obstetrician and Gynaecologist at the
Bristol Maternity Hospital

Mrs J Humphrey
Retired Midwife, Bristol

Dr J Keeling
Paediatric Pathology Department, Royal Hospital for
Sick Children, Edinburgh

Mrs Margaret Inglis
Counsellor, Royal Free Hospital, London

Ms J Kerr
Clinical Nurse Specialist (Infertility), Leeds

Miss P Lamburn
Formerly Editorial Director, IPC Magazines.
Chairman, General Advisory Council to the IBA
(1982 - 1985). Also a former member of the ILA

Dr H Leese
Director, Department of Biology, University of York

Dr E Lenton
Scientist, Jessop Hospital for Women, Sheffield

Dr J D O Loudon
Member of the General Medical Council. Formerly
Consultant Obstetrician and Gynaecologist,
Edinburgh and Chairman of the RCOG Ethics
Committee. Formerly a member of the ILA

Professor Sir Malcolm MacNaughton
Formerly President of the RCOG and a member of
the ILA. Formerly Professor of Obstetrics and
Gynaecology, Glasgow Royal Infirmary

Dr J Mills
Consultant Gynaecologist, Ninewells Hospital

Professor N Nevin
Consultant in Medical Genetics, The Queens
University of Belfast

Professor J Newton
Head of Department of Obstetrics and Gynaecology,
Birmingham Maternity Hospital

Ms Vicki Nix
Royal College of Nursing

Sir John Osborn
Formerly Conservative MP for Hallam and a member
of the Parliamentary Assembly of the Council of
Europe. Also a former member of the ILA

Dr J Packman
Retired University Teacher and Researcher,
University of Essex

Ms Katherine Parkinson
Nurse Manager, AMI Portland Hospital, London

Mr J Parsons
Consultant Gynaecologist, King's College Hospital,
London

Dr M Patten
Regional Genetics Centre, St George's Hospital,
London

Professor C Rodeck
Dept. of Obstetrics and Gynaecology, University
College Hospital, London

Miss J Robb
SRN, Qualified Midwife and Health Visitor, Devon

Mr R Sawers
Birmingham and Midland Hospital for Women

Ms A Sayburn
Director, AMI Portland Hospital, London

Dr M Seller
Cell Biologist, Dept. of Paediatric Research, Guys
Hospital, London

Mrs F Sieghart
Justice of the Peace, London

Mrs E Snowden
Institute of Population Studies, University of Exeter

Ms J Spiers
Director, Family Care Social Work Agency,
Edinburgh

Mrs B Symons
Freelance Consultant Trainer

Professor A Templeton
Clinician, Dept of Obstetrics and Gynaecology,
Aberdeen Maternity Hospital

Professor E J Thomas
Princess Anne Hospital, Southampton

Professor W Thompson
Professor of Obstetrics and Gynaecology, Queens
University, Belfast. Formerly a member of the ILA
and Chairman of the RCOG Fertility Sub-Committee

Mr W R Thompson
Treasurer, Association of Community Health
Councils

Mr T Timlett
Manager, Exeter and District Marriage Guidance
(RELATE)

Mrs P Vogt
Team Manager, Oxfordshire Social Services
Department

Mr P Wardle
Consultant Senior Lecturer, Bristol Maternity
Hospital

